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INSTITUTIONAL REVIEW BOARD/
COMMITTEE ON HUMAN RESEARCH

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June 29, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 00D-0805: Exception from Informed Consent Requirements for Emergency Research

To Whom It May Concern:

I apologize for the lateness of this response to your request for commentary; I understand from a colleague that you have extended the deadline to the end of June, and so I would like to make some very simple comments.

I have circulated the guidance document among those of our staff who were involved in the U.S. DCLHb Trauma trial. They had little to add to the document, which they found well-written, comprehensive and clear. They did have a concern with the guidelines concerning the type and frequency of community consultation listed on page 8, and specifically with the suggestion that IRB members attend any community meetings or other events intended to publicize the study. Our IRB members are faculty volunteers who already spend a minimum of four hours per week completing their regular duties. This level of direct involvement of the IRB would simply not be feasible for us. We might suggest instead that community meetings be audio or videotaped, so that they might at least be reviewed at a time convenient to the IRB member.

Thank you for the opportunity to comment on the proposed guidance.

Yours sincerely,

Charlotte L. Shupert

Charlotte L. Shupert, Ph.D.
Compliance Manager

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